

REMARKS

In the office action, claims 1, 2, 6-16, 19, 20, 22, and 24 were rejected.
Reconsideration and allowance of all pending claims is respectfully requested.

Rejections Under 35 U.S.C. §103

In the office action, the examiner rejected claims 1, 6, 11-16, and 19-24 under 35 U.S.C. §103(a) as being unpatentable over Yokoi et al., U.S. Patent No. 6,972,565, (hereinafter “Yokoi”) in view of Kaseya, *Virtual System Administrator*, (hereinafter “Kaseya”). The examiner rejected claims 2 and 9 under 35 U.S.C. §103(a) as being unpatentable over Yokoi in view of Kaseya in further view of Krasner, U.S. Patent No. 5,825,327, (hereinafter “Kasner”). The examiner rejected claim 7 under 35 U.S.C. §103(a) as being unpatentable of Yokoi in view of Kaseya in further view of the manual published by the FDA last revised 01/01/97 entitled “Quality System Manual”, (hereinafter “FDA”). The examiner rejected claims 8 and 10 under 35 U.S.C. §103(a) as being unpatentable over Yokoi in view of Kaseya in further view of “Reliable Design of Medical Devices” by Richard C. Fries, (hereinafter “Fries”). The applicants respectfully traverse these rejections.

Legal Precedent

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). However, a claimed invention composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). The *KSR* court stated that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new

invention does ... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* Specifically, there must be some articulated reasoning with a rational underpinning to support a conclusion of obviousness; a conclusory statement will not suffice. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Indeed, the factual inquiry determining whether to combine references must be thorough and searching, and it must be based on objective evidence of record. *In re Lee*, 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002).

Furthermore, there must be some reason to combine references other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044 (Fed. Cir. 1988). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). The Federal Circuit has warned that the Examiner must not, “fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.” *In re Dembiczak*, F.3d 994, 999 (Fed. Cir. 1999) (quoting *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)).

In addition, the pending claims must be given an interpretation that is reasonable and consistent with the *specification*. See *In re Prater*, 415 F.2d 1393, 1404-05, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969); see also *In re Morris*, 127 F.3d 1048, 1054-55, 44 U.S.P.Q.2d 1023, 1027-28 (Fed. Cir. 1997); see also M.P.E.P. §§ 608.01(o) and 2111. Indeed, the specification is “the primary basis for construing the claims.” See *Phillips v. AWH Corp.*, 415 F.3d 1303 (2005) (*en banc*). One should rely *heavily* on the written description for guidance as to the meaning of the claims. See *id.*

Interpretation of the claims must also be consistent with the interpretation that *one of ordinary skill in the art* would reach. See *In re Cortright*, 165 F.3d 1353, 1359, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999); M.P.E.P. § 2111. “The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation.” See *Collegenet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 75 U.S.P.Q.2d 1733, 1738 (Fed. Cir. 2005) (quoting *Phillips v. AWH Corp.*, 75 U.S.P.Q.2d 1321, 1326). The Federal Circuit has made clear that derivation of a claim term must be based on “usage in the ordinary and accustomed meaning of the words amongst artisans of ordinary skill in the relevant art.” See *id.*

Deficiencies in the rejection of independent claims 1, 6, 12, and 15

Turning to the claims, independent claims 1, 6, 12, and 15 recite in generally similar language, *inter alia*, wherein the medical device is operable to detect an alteration of at least one of medical device hardware and medical device software by a service provider. In the present office action, the examiner rejected claims 1, 6, 12, and 15 citing the combination of Yokoi with Kaseya. However, as discussed below, neither of the cited references alone or in combination, teaches, discloses, suggests or even contemplates such operability.

As the Examiner correctly pointed out, Yokoi does not teach that the medical device is operable to detect an alteration of at least one of medical device hardware and medical device software. See Office Action, pg. 6. Moreover, Kaseya fails to obviate the deficiency of Yokoi. By way of contrast, Kaseya teaches that a monitor may be used to receive “instant notification when ... a user removes or adds a PCI card.” See Kaseya, pg. 2. Assuming, *arguendo*, that Kaseya’s Microsoft NT Server teachings would be considered analogous art to a medical device such as an MRI (an assumption that applicants, in fact, reject), the Kaseya teachings are directed to computer users only. In the final office action, the examiner improperly changed the definition of “service provider” as found in the

specification and as understood by a person of ordinary skill in the art, into that of a “computer user.” More specifically, the examiner stated that the “[a]pplicant does not provide a special definition of a ‘service provider’, Examiner defines the term as ‘a person who performs a service on a device’. The user of Kaseya fits this description as the user adds and removes hardware or software on the device.” See office action, Pg. 2. In response to the examiner’s assertion, the applicants offer the following remarks.

The examiner’s interpretation of “service provider” is inconsistent with the specification

First, the applicants respectfully note that the claim recitation of the term “service provider” must be given an interpretation that is reasonable and consistent with the specification. See *In re Prater*, 415 F.2d 1393. Indeed, the specification is “the primary basis for construing the claims.” See *Phillips v. AWH Corp.*, 415 F.3d 1303. The specification clearly defines “service provider” as person responsible for servicing complex medical devices. More specifically, the specification states that “[i]n the illustrated embodiment, the method begins with a service provider, such as a field engineer or an on-line engineer, receiving a request for service on the medical imaging system 22, represented generally by block 54.” See specification, Pg. 6, lines 16-19. Likewise, the specification recites “[h]owever, many medical systems, such as medical imaging systems, are complex machines. As a result, they may require periodic servicing from a service provider.” See specification, Pg. 1, lines 22-23. Other similar qualifications may be found throughout the specification: “[p]eriodically, a service may need to be performed on the medical imaging system 22 by a service provider. For example, the services of a service provider may be retained to improve the images produced by the medical imaging system 22.” See specification, Pg. 3, lines 13-16. It simply cannot be said that the applicants have not provided a definition for a service provider. Indeed, the specification contains many references to the term, such as those quoted above, describing a service provider as a person responsible for servicing complex medical

devices, for example, a field engineer. Accordingly, a service provider as recited by the claims is clearly different than the average computer user of Kaseya. Unlike the average computer user, a qualified professional service provider has been trained and is capable of servicing complex medical machinery. If a user could do so, the service provider would be unnecessary. It simply cannot be said that a computer user is analogous to a trained and experienced service provider.

The examiner's interpretation of "service provider" is inconsistent with the interpretation in the art

Interpretation of the claims must also be consistent with the interpretation that one of ordinary skill in the art would reach. *See In re Cortright*, 165 F.3d 1353. *See also*, M.P.E.P. § 2111. A person of ordinary skill in the art would not equate the term "service provider" with the term "user" as suggested by the examiner. Indeed, the examiner's own proffered reference material clearly suggests otherwise. For example, the service personnel section of the FDA Quality Systems Manual offered by the examiner as a reference defines "service personnel", (i.e., service providers) as "trained and experienced personnel" capable of "handling, diagnosis, and repair" of medical devices. *See FDA*, pgs. 2-3. Additionally, the service personnel section of the FDA manual references 21 C.F.R. § 820.25(b), Medical Devices, Quality Systems Regulation, which states that "[e]ach manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented." *See* 21 C.F.R. § 820.25(b) (emphasis added). It is quite clear from the examiner's proffered references that a "service provider", (i.e., service personnel), is typically a highly trained individual capable of handling, diagnosing, and repairing complex medical devices. By way of contrast, the typical computer user has no such training or experience. Indeed, the term computer user is defined as "a person who uses a computer." *See* Dictionary.com; available at

<http://dictionary.reference.com/browse/user>. It appears that the examiner has improperly redefined the term “service provider” solely to allege unpatentability in view of Kaseya.

The art fails to teach generating a service report based on medical device data and service provider data

In addition, independent claim 1 recites, *inter alia*, “operating the computer system to generate a service report based on a combination of the medical device data and the service provider data” (emphasis added). A similar feature is recited by independent claims 6, and 15. Neither Yokoi nor Kaseya teach or even contemplate “operating the computer system to generate a service report based on a combination of the medical device data and the service provider data.” Indeed, both Yokoi and Kaseya fail to enable the claimed subject matter, and in fact, are clearly missing teachings of claim recitations. As mentioned above, Kaseya does not provide any teaching of servicing by service providers. Further, the data in Kaseya’s teachings consists of general purpose computer data only (i.e., Windows NT server or desktop). Indeed, there is no mention whatsoever of medical device data, e.g., information such as MRI images, medical imaging modalities, and so forth, is nowhere to be found in Kaseya. Yokoi does not obviate this deficiency. A careful review of Yokoi shows that, at most, Yokoi teaches the storing of MRI related data (e.g., errors that occur during MRI operations, manufacturer alerts), and not the generating of reports based on a combination of medical device data and the service provider data.

Accordingly, the Yokoi and Kaseya teachings at the very least fail to enable the claimed subject matter, and indeed fail to disclose each element of the independent claims 1, 6, 12, and 15. For at least these reasons, among others, Applicants submit that Yokoi and Kaseya cannot support a *prima facie* case of obviousness, and that the rejection should be withdrawn. Applicants therefore respectfully request withdrawal of the rejections under 35 U.S.C. § 103 and allowance of claims 1, 6, 12, and 15 as well as those claims depending therefrom.

The remaining secondary references have also been fully reviewed, and also do not obviate the deficiencies of the primary references discussed above.

Conclusion

In view of the remarks and amendments set forth above, the applicants respectfully request allowance of the pending claims. If the examiner believes that a telephonic interview will help speed this application toward issuance, the examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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